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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/611,652	07/07/2000	Richard J. Zeman	001290.091198	8034

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EXAMINER	
HUI, SAN MING R	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 08/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/611,652	ZEMAN ET AL.	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,8,10 and 37-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,8,10 and 37-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendments filed March 31, 2004 have been entered. The addition of claims 47-51 is acknowledged.

Claims 1-5, 8, 10, 37-51 are pending.

The outstanding rejection under 35 USC 112, first paragraph is withdrawn in view of applicant's remarks filed March 31, 2004.

The outstanding rejection under 35 USC 102(b) in reference to Vaidyanathan et al. is withdrawn in view of applicant's remarks filed March 31, 2004.

Upon an update search before allowing claims, Examiner identifies new art and a new ground of rejection is set forth below.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-3 and 38-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2-3, 38-39, and 50-51 contain the trademark/trade name "BRL-47672". Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade

name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a β2-agonist and, accordingly, the identification/description is indefinite.

Response to arguments

Applicant's arguments filed March 31, 2004 averring the recitation of "BRL-47672" as clear in view of the incorporation of US 6,015,837 have been considered, but are not found persuasive. US 6,015,837 only disclose the chemical structure of "MJ-9184-1", "QH-25", and "R-804". It does not disclose the chemical structure of "BRL-47672" although "BRL-47672" is recited in the claim. Since it is not clear to one of ordinary skill in the art what "BRL-47672" is, the claims are indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 5, 8, 37, 41-44, and 47-49 are rejected under 35 U.S.C. 102(a) as being anticipated by Murphy et al. (Arch. Phys. Med. Rehabil., 1999;80(10):1264-1267).

Murphy et al. teaches a method of employing salbutamol in dosage of 2mg twice daily in spinal cord injury patients to improve the functional electrical stimulation training in these patients (See the abstract and page 1264, col. 1, Subjects and Methods Section).

Applicants' attention is directed to *Ex parte Novitski*, 26 USPQ2d 1389 (BOPA 1993) illustrating anticipation resulting from inherent use, absent a *haec verba* recitation for such utility. In the instant application, as in *Ex parte Novitski*, supra, the claims are directed to treating a malady or disease with old and well known compounds or compositions. It is now well settled law that administering compounds inherently possessing a protective or treatment utility anticipates claims directed to such protective use. Arguments that such protective use is not set forth *haec verba* are not probative. Prior use for the same utility clearly anticipates such utility, absent limitations distancing the proffered claims from the inherent anticipated use. Attempts to distance claims from anticipated utilities with specification limitations will not be successful. At page 1391, *Ex parte Novitski*, supra, the Board said "We are mindful that, during the patent examination, pending claims must be interpreted as broadly as their terms reasonably allow. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989). As often stated by the CCPA, "we will not read into claims in pending applications limitations from the specification." *In re Winkhaus*, 52 F.2d 637, 188 USPQ 219 (CCPA 1975).". In the instant application, Applicants' failure to distance the proffered claims from the anticipated treatment utility, renders such claims anticipated by the prior inherent use.

Response to arguments

Applicant's arguments filed March 31, 2004 averring Murphy et al.'s teaching away have been considered, but are not found persuasive. Murphy et al. clearly teaches the total workload output significantly increased in salbutamol group (See Page 1265, col. 2, Result Section). Such results support the previous reports that salbutamol increases voluntary muscle strength in upper extremities. See page 1266, col. 1, last paragraph bridging col. 2). Therefore, Murphy is not seen to be teaching away.

Applicant's arguments filed March 31, 2004 averring Murphy's failure to teach the use of β2-agonist to reduce spinal cord injury-induced loss of spinal cord tissue and prevent resulting paralysis and loss of locomotor function have been considered, but are not found persuasive. Those therapeutic effects are considered inherently present in the method of Murphy since Murphy teaches the administration of the herein claimed β2-agonist to the same patient (i.e., patients suffered from spinal cord injury).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Murphy et al. as applied to claims 1-3, 5, 8, 37-39, 41-44, and 47-49 above.

Muphy does not expressly teach the dosage of salbutamol as 0.25mg/day per kg body weight.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust the dosage of salbutamol to 0.25mg/day per kg body weight.

One of ordinary skill in the art would have been motivated to adjust the dosage of salbutamol to 0.25mg/day per kg body weight. The optimization of result effect parameters (e.g., dosage range) is obvious as being within the skill of the artisan.

Response to arguments

Applicant's arguments with regard to patentability of claim 10, which depending upon the arguments above, have been considered, but are not found persuasive. The arguments have been addressed above.

New ground of rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5, 8, 10, 37-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone et al. (US Patent 5,281,607).

Stone et al. teaches a method of treating spinal cord injury and motor degenerating diseases such as ALS, infantile spinal muscular atrophy, and juvenile spinal muscular atrophy by employing β-agonists, including dobutamine, clenbuterol, salbutamol, terbutaline, and fenoterol (See col. 4, lines 14-25, 62-66 and col. 5, line15). Stone et al. also teaches the dosage of β-agonists employed as 0.01 to 100mg/kg of body weight (See col. 6, line 46).

Stone et al. does not expressly teach the dosage employed as 0.5 to 100μg/kg, 0.5 to 1000μg/kg, 0.04 mg/kg, or 0.25mg/day per kg of body weight.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust the dosage of β-agonists to the herein claimed amount.

One of ordinary skill in the art would have been motivated to adjust the dosage of β-agonists to the herein claimed amount. The optimization of result effect parameters (e.g., dosage range) is obvious as being within the skill of the artisan, absent evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

San-ming Hui
Patent Examiner
Art Unit 1617